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Inconsistencies in the planning of the duration of anticoagulation among outpatients with acute deep-vein thrombosis. Results from the OTIS-DVT registry

Spirk, D ; Husmann, M ; Willenberg, T ; Banyai, M ; Frank, U ; Baldi, T ; Amann-Vesti, B ; Baumgartner, I ; Kucher, N

Abstract: Three-month anticoagulation is recommended to treat provoked or first distal deep-vein thrombosis (DVT), and indefinite-duration anticoagulation should be considered for patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT. In the prospective Outpatient Treatment of Deep Vein Thrombosis in Switzerland (OTIS-DVT) Registry of 502 patients with acute objectively confirmed lower extremity DVT (59% provoked or first distal DVT; 41% unprovoked proximal, unprovoked recurrent, or cancer-associated DVT) from 53 private practices and 11 hospitals, we investigated the planned duration of anticoagulation at the time of treatment initiation. The decision to administer limited-duration anticoagulation therapy was made in 343 (68%) patients with a median duration of 107 (interquartile range 91-182) days for provoked or first distal DVT, and 182 (interquartile range 111-184) days for unprovoked proximal, unprovoked recurrent, or cancer-associated DVT. Among patients with provoked or first distal DVT, anticoagulation was recommended for <3 months in 11%, 3 months in 63%, and for an indefinite period in 26%. Among patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT, anticoagulation was recommended for <6 months in 22%, 6-12 months in 38%, and for an indefinite period in 40%. Overall, there was more frequent planning of indefinite-duration therapy from hospital physicians as compared with private practice physicians (39% vs. 28%; p=0.019). Considerable inconsistency in planning the duration of anticoagulation therapy mandates an improvement in risk stratification of outpatients with acute DVT.

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Inconsistencies in the planning of the duration of anticoagulation among outpatients with acute deep-vein thrombosis

Results from the OTIS-DVT Registry

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Summary

Three-month anticoagulation is recommended to treat provoked or first distal deep-vein thrombosis (DVT), and indefinite-duration anticoagulation should be considered for patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT. In the prospective Outpatient Treatment of Deep Vein Thrombosis in Switzerland (OTIS-DVT) Registry of 502 patients with acute objectively confirmed lower extremity DVT (59% provoked or first distal DVT; 41% unprovoked proximal, unprovoked recurrent, or cancer-associated DVT) from 53 private practices and 11 hospitals, we investigated the planned duration of anticoagulation at the time of treatment initiation. The decision to administer limited-duration anticoagulation therapy was made in 343 (68%) patients with a median duration of 107 (interquartile range 91–182) days for provoked or first distal DVT, and 182 (interquartile range 111–184) days for unprovoked proximal, unprovoked recurrent, or cancer-associated DVT. Among patients with provoked or first distal DVT, anticoagulation was recommended for <3 months in 11%, =3 months in 63%, and for an indefinite period in 26%. Among patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT, anticoagulation was recommended for <6 months in 22%, 6–12 months in 38%, and for an indefinite period in 40%. Overall, there was more frequent planning of indefinite-duration therapy from hospital physicians as compared with private practice physicians (39% vs. 28%; p=0.019). Considerable inconsistency in planning the duration of anticoagulation therapy mandates an improvement in risk stratification of outpatients with acute DVT.

Keywords

Deep-vein thrombosis, anticoagulants, outpatient treatment

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Introduction

The annual incidence of acute symptomatic deep-vein thrombosis (DVT) varies between 220,000–400,000 in the United States and exceeds 460,000 in six large European Union countries (1–4). After discontinuation of anticoagulation therapy, the risk of recurrence within 12 months ranges between 5% and 10% in patients with venous thromboembolism (VTE) provoked by a transient risk factor, including surgery, hospitalisation, immobilisation, oestrogen therapy, pregnancy, or prolonged travel (5–7). However, in patients with unprovoked or idiopathic VTE, the risk of recurrence is substantially higher and ranges between 15% and 30% (7–10). In addition, thrombosis localisation (distal or proximal) and episode (first or subsequent) modify the risk of recurrence (9–13). In patients with provoked VTE, three-month anticoagulation therapy halves the risk of recurrence within the next year in comparison to shorter treatment periods (5, 9, 10). In comparison to placebo, indefinite-duration therapy with conventional-intensity vitamin K antagonists (international normalised ratio [INR] target 2.5, range 2.0–3.0) reduces the risk of thrombosis recurrence by up to 90% in patients with unprovoked VTE (11, 14). According to current consensus guidelines of the American College of Chest Physicians (ACCP), patients with provoked or first distal DVT should receive anticoagulation treatment for three months, and in patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT indefinite-duration anticoagulation therapy should be considered (15). For each individual patient, the benefits of indefinite-duration anticoagulation therapy should be balanced against the risk of bleeding and its indication reassessed on a regular basis (16). The 2008 ACCP recommendations for the duration of anti-

coagulation were accepted by the Swiss Expert Group (17). In the prospective Outpatient Treatment of Deep Vein Thrombosis in Switzerland (OTIS-DVT) Registry, we investigated the planned duration of anticoagulation therapy in DVT outpatients at the time of treatment initiation.

Methods

Patients

Overall, 502 consecutive patients ≥18 years of age who were treated for acute objectively confirmed lower extremity DVT with or without pulmonary embolism (PE) on an outpatient basis and received antithrombotic therapy for at least five days were enrolled in the prospective OTIS-DVT Registry. Emergency department physicians and vascular medicine physicians from eleven Swiss hospitals as well as vascular medicine physicians, internal medicine physicians or general practitioners from 53 private practices participated in the study and recruited patients during outpatient visits between March 1, 2009 and March 31, 2010. The exclusion criteria were acute PE without DVT, untreated clinically suspected acute DVT, and DVT with subsequent hospitalisation. Accepted tests to objectively confirm DVT included compression ultrasound and conventional phlebography, and PE imaging tests included contrast-enhanced chest computed tomography, ventilation perfusion scan, or conventional pulmonary angiography. OTIS-DVT did not issue any recommendations for the diagnosis and treatment of DVT. The study was approved by the ethics committees in all participating cantons according to local regulations in Switzerland.

Data, definitions and statistical analysis

Anonymous data were prospectively collected using a standardised case report form (CRF): specifically, information on patient age, sex, weight, height, localisation and episode of DVT, confirmatory test of VTE diagnosis, risk factors for VTE, such as surgery within 30 days, immobilisation defined as <30 minutes (min) walk per day for more than three days, active cancer, acute medical illnesses, contraceptive or substitutive hormonal therapy, pregnancy, recent prolonged travel, and the planned duration of pharmacological treatment. Thrombosis categorisation as provoked or unprovoked was based on the assessment of VTE risk factors according to the ACCP guidelines criteria (15); the CRF itself did not mandate categorisation of thrombosis as provoked or unprovoked. Physicians were asked to provide the initiation and termination dates indicating the planned duration of anticoagulation. No termination date had to be provided in case of planned indefinite-duration anticoagulation therapy. Data were entered solely by the treating physician.

Patients were divided into two groups according to the duration of anticoagulation selected by the physician: the first group consisted of patients with limited-duration anticoagulation defined as the presence of an exact date range for the duration of anticoagulation treatment; the second group consisted of patients with planned indefinite-duration anticoagulation therapy defined as long-term treatment without a planned termination date. According to the ACCP consensus guidelines (15), we also grouped the patients into those with an indication for three-month anticoagulation therapy, comprising provoked or first distal DVT, and patients with an indication for indefinite-duration anticoagulation therapy, comprising those with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT. Provoked DVT was defined as DVT associated with surgery, hospitalisation, immobilisation for more than three days, oestrogen therapy, pregnancy, or prolonged (>5 hours h) travel, all within 30 days prior to VTE diagnosis (15). For cancer-associated DVT, the ACCP guidelines recommend anticoagulation indefinitely or until the cancer is resolved (15). Since cancer cure is unpredictable, we considered indefinite-duration anticoagulation to be the most suitable initial recommendation for cancer-associated DVT. Patients with combined proximal and distal DVT were analysed in the proximal DVT group.

Discrete variables are presented as frequencies and percentages, and group comparisons were performed using the chi-square or Fisher's exact test. Continuous variables with a normal distribution are described as means with standard deviations, and group comparisons were performed with the t-test; continuous variables with skewed distribution are presented as medians with interquartile ranges (IQR), and group comparisons were performed using the Wilcoxon ranksum test. All reported p-values are two tailed. Data were analysed using STATA 10 software (STATACorp LP, College Station, TX, USA). Data collection and database entry was performed by an independent data coordinating center (la volta statistics, Zurich, Switzerland).

Results

Patient characteristics

Among the 502 enrolled patients, the mean age was 58 ± 17 years, 55% were women, the mean weight was 78.3 ± 15.9 kg, and the mean body mass index (BMI) 27.2 ± 5.1 kg/m^2 (▶Table 1). Overall, 168 (33%) patients were enrolled from hospital physicians in an emergency department, and 334 (67%) from private practice physicians; 140 (28%) were hospitalised within 30 days prior to enrolment, 103 (21%) were obese with BMI >30 kg/m^2, 94 (19%) immobile for >3 days, 62 (12%) had surgery within 30 days, and 53 (11%) active cancer. One per cent patients had a creatinin-clearance of less than 30 ml/min, 1% active bleeding, and none had heparin-allergy or heparin induced thrombocytopenia prior to enrolment.

In total, 294 (59%) patients had provoked or first distal DVT, and 208 (41%) unprovoked proximal, unprovoked recurrent, or cancer-associated DVT. Proximal DVT was diagnosed in 227 (45%) patients, isolated distal DVT in 218 (44%), and DVT with concomitant symptomatic PE in 57 (11%). In total, 379 (75%) pa-

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Table 1: Patient characteristics according to the planned duration of anticoagulation treatment.

	Total N = 502	Limited-duration anti-coagulation therapy N = 343	Indefinite-duration anti-coagulation therapy N = 159	P-value
Age, years ± SD	57.8 ± 17.0	57.9 ± 16.4	57.7 ± 18.1	0.90
Women, n (%)	273 (55.2)	185 (54.7)	88 (56.1)	0.78
Weight, kg ± SD	78.3 ± 15.9	79.5 ± 15.9	75.6 ± 15.7	0.017
BMI, kg/m^2 ± SD	27.2 ± 5.1	27.5 ± 5.0	26.5 ± 5.4	0.07
Proximal DVT, n (%)	227 (45.2)	158 (46.1)	69 (43.4)	0.58
Isolated distal DVT, n (%)	218 (43.4)	140 (40.8)	78 (49.1)	0.08
DVT with concomitant PE, n (%)	57 (11.4)	45 (13.1)	12 (7.5)	0.07
Recurrent DVT, n (%)	123 (24.5)	76 (22.2)	47 (29.6)	0.07
Provoked DVT, n (%)	252 (50.2)	192 (56.0)	60 (37.8)	<0.001
Unprovoked first distal DVT, n (%)	70 (14.0)	38 (11.1)	32 (20.1)	0.006
Unprovoked first proximal DVT, n (%)	93 (18.5)	65 (18.9)	28 (17.6)	0.72
Unprovoked recurrent DVT, n (%)	87 (17.3)	48 (14.0)	39 (24.5)	0.004
Prior hospitalisation within 30 days, n (%)	140 (27.9)	110 (32.1)	30 (18.9)	0.002
Obesity, n (%)	103 (20.5)	76 (22.2)	27 (17.0)	0.18
Bed rest >3 days within 30 days, n (%)	94 (18.7)	73 (21.3)	21 (13.2)	0.031
Surgery within 30 days, n (%)	62 (12.4)	52 (15.2)	10 (6.3)	0.005
Active cancer, n (%)	53 (10.6)	20 (5.8)	33 (20.8)	<0.001

BMI, body mass index; DVT, deep-vein thrombosis; n, number; PE, pulmonary embolism; SD, standard deviation.

tients had the first episode of acute DVT, 78 (16%) had ipsilateral and 45 (9%) contralateral DVT recurrence. DVT was unprovoked in 250 (50%) patients.

Planned duration of anticoagulation

The decision to administer limited-duration anticoagulation therapy was made in 343 (68%) patients with a median duration of 107 (IQR 91–182; mean ± SD 139 ± 71) days for provoked or first distal DVT, and 182 (IQR 111–184; mean ± SD 197 ± 128) days for unprovoked proximal, unprovoked recurrent, or cancer-associated DVT (▶Fig. 1). In comparison to patients with limited-duration anticoagulation therapy, the 159 (32%) patients with planned indefinite-duration anticoagulation therapy more frequently had unprovoked DVT (62% vs. 44%, p <0.001), active cancer (21% vs. 6%, p<0.001), were leaner (76 vs. 80 kg, p=0.017), and were less often hospitalised within 30 days prior to enrolment (19% vs. 32%, p=0.002), had surgery within 30 days (6% vs. 15%, p=0.005), or immobilisation for more than three days (13% vs. 21%, p=0.031). A high proportion of patients with first distal DVT received a prescription for extended anticoagulation therapy beyond three months or for an indefinite period (▶Table 2).

Among patients with provoked or first distal DVT, anticoagulation was recommended for <3 months in 11%, ≥3 months in

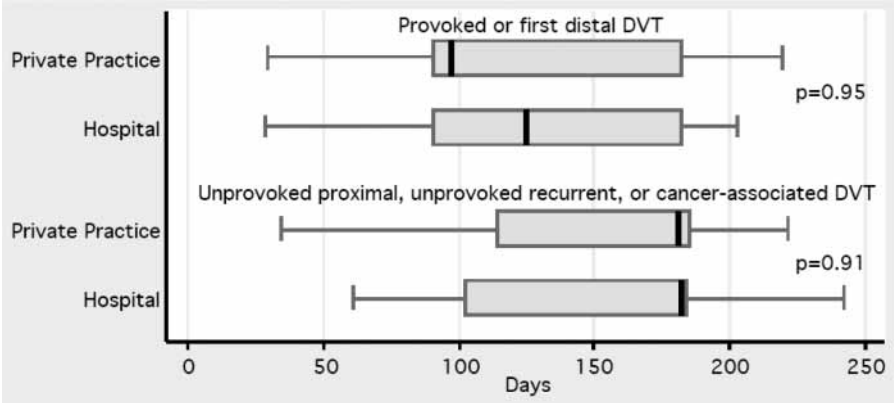

Figure 1: Planned duration of anticoagulation treatment in patients with limited-duration anticoagulation. The box plots display the median and interquartile range (IQR, the 25th-75th percentiles), and the whiskers display the upper and lower values within 1.5 times the IQR beyond the 25th-75th percentile. DVT, deep-vein thrombosis.

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63%, and for an indefinite period in 26% (▶Table 3). Among patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT, anticoagulation was recommended for <6 months in 22%, 6–12 months in 38%, and for an indefinite period in 40%. Overall, there was a trend towards more frequent plan for the indefinite-duration therapy from hospital physicians as compared with private practice physicians (39% vs. 28%; p=0.019).

Discussion

The present analysis from the prospective OTIS-DVT Registry showed a large variation in the planned duration of anticoagulation treatment suggesting that there was considerable inconsistency with current consensus guidelines. In total, 63% of the patients with provoked or first distal DVT received a prescription of

Event	Total	Provoked	Unprovoked	P-value
All DVT, n (%)	502 (100.0)	252 (50.2)	250 (49.8)	
<3 months (90 days)	38 (7.6)	26 (10.3)	12 (4.8)	0.027
≥3 to <6 months (90–180 days)	142 (28.3)	82 (32.6)	60 (24.0)	0.038
≥6 months (>180 days)	163 (32.5)	84 (33.3)	79 (31.6)	0.70
Indefinite	159 (31.6)	60 (23.8)	99 (39.6)	<0.001
First distal DVT, n (%)	176 (100.0)	106 (60.2)	70 (39.8)	
<3 months (90 days)	27 (15.3)	19 (17.9)	8 (11.4)	0.29
≥3 to <6 months (90–180 days)	72 (40.9)	49 (46.2)	23 (32.9)	0.09
≥6 months (>180 days)	16 (9.1)	9 (8.5)	7 (10.0)	0.79
Indefinite	61 (34.7)	29 (27.4)	32 (45.7)	0.015
First proximal DVT, n (%)	203 (100.0)	110 (54.2)	93 (45.8)	
<3 months (90 days)	6 (3.0)	5 (4.6)	1 (1.1)	0.22
≥3 to <6 months (90–180 days)	44 (21.7)	27 (24.5)	17 (18.3)	0.31
≥6 months (>180 days)	102 (50.2)	55 (50.0)	47 (50.5)	1.00
Indefinite	51 (25.1)	23 (20.9)	28 (30.1)	0.15
Recurrent DVT, n (%)	123 (100.0)	36 (29.3)	87 (70.7)	
<3 months (90 days)	5 (4.1)	2 (5.6)	3 (3.5)	0.63
≥3 to <6 months (90–180 days)	26 (21.1)	6 (16.7)	20 (23.0)	0.48
≥6 months (>180 days)	45 (36.6)	20 (55.5)	25 (28.7)	0.007
Indefinite	47 (38.2)	8 (22.2)	39 (44.8)	0.025

DVT, deep-vein thrombosis.

Table 2: Planned duration of anticoagulation treatment of provoked and unprovoked DVT.

Event	Total N = 502	Hospital N = 168	Private practice N = 334	P-value
Provoked or first distal DVT, n (%)	294 (100.0)	91 (31.0)	203 (69.0)	
<3 months (90 days)	32 (10.9)	10 (11.0)	22 (10.8)	1.00
≥3 to <6 months (90–180 days)	102 (34.7)	30 (33.0)	72 (35.5)	0.69
≥6 months (>180 days)	85 (28.9)	23 (25.3)	62 (30.5)	0.41
Indefinite	75 (25.5)	28 (30.7)	47 (23.2)	0.19
Unprovoked proximal, unprovoked recurrent, or cancer-associated DVT, n (%)	208 (100.0)	77 (37.0)	131 (63.0)	
<3 months (90 days)	6 (2.9)	2 (2.6)	4 (3.0)	1.00
≥3 to <6 months (90–180 days)	40 (19.2)	12 (15.6)	28 (21.4)	0.36
≥6 months (>180 days)	78 (37.5)	26 (33.8)	52 (39.7)	0.46
Indefinite	84 (40.4)	37 (48.0)	47 (35.9)	0.11

DVT, deep-vein thrombosis; n, number.

Table 3: Planned duration of anticoagulation treatment in hospitals and private practices.

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anticoagulants for three or more months. Although the ACCP 2008 guidelines (15) do not recommend prolonged anticoagulation beyond three months in patients with provoked proximal DVT, it may be justified in patients with extensive iliofemoral DVT. However, the finding that one third of the patients with first distal DVT were assigned to the indefinite-duration anticoagulation therapy is concerning. In contrast, we found that only 40% of patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT were considered for an indefinite-duration anticoagulation therapy. Overall, these findings suggest that the decision on planning the duration of anticoagulation was often arbitrary rather than guideline-based.

There were few differences in clinical characteristics between patients with the limited-duration and the indefinite-duration anticoagulation therapy, including a higher rate of provoked DVT and less frequent active cancer in patients with limited-duration anticoagulation therapy. We believe that 1) patient, 2) physician, and 3) guideline factors contributed to the observed gap between our findings and current recommendations. Patient factors that likely affected the decision on the duration of anticoagulation treatment include the presence of medical co-morbidities, a history of bleeding complications or an increased risk of bleeding, patient preferences, and prior difficulties with anticoagulation monitoring. Because OTIS-DVT was a prospective study recruiting patients entirely managed on an outpatient basis, it is less likely that patient factors were the main reason for the observed gap between guidelines and clinical practice. Physician factors are difficult to assess but likely had major impact on our findings: physician preferences, unawareness of the importance of whether the DVT was provoked or unprovoked, and unawareness of specific recommendations from the current ACCP consensus guidelines (15) and the Swiss Expert Group (17). Finally, current guidelines may have contributed to some extent because they do not specifically comment on the duration of anticoagulation in certain subsets of patients, including provoked extensive iliofemoral DVT, provoked recurrent DVT, or first distal DVT in cancer patients.

In our study, the patient characteristics were similar to those previously reported in other observational studies: Proximal DVT was diagnosed in 45% of patients in the present study, 42% in the Optimisation de l'interrogatoire dans l'évaluation du risque thrombo-embolique veineux (OPTIMEV) study (18) and 48% in a study by Prandoni et al. (7). Recurrent DVT was present in 25% of patients in the current study and 18% in the Swiss Venous Thromboembolism Registry (SWIVTER) (19). The proportion of patients with provoked DVT was slightly higher in OTIS-DVT (50%) than in previous clinical trials (35–40%) evaluating different strategies on the duration of anticoagulation therapy (9–11). In comparison to hospitalised VTE patients from the SWIVTER registry (19), the OTIS-DVT patients appeared to be younger (58 vs. 62 years) and less often had co-morbidities. However, similar rates of active cancer (15%) and concomitant PE (16%) were found among patients with the first episode of symptomatic DVT (7). Clinical practice data reporting the duration of anticoagulation in DVT patients is rather scarce. Among inpatients enrolled in the Registro Informatizado de la Enfermedad TromboEmbolica venosa (RIETE) registry (20), 89% of patients with distal DVT and 92% with proximal DVT received anticoagulation treatment for at least three months. In a prospective cohort study of 1,600 patients with the first VTE episode without cancer, 17% were treated with oral anticoagulation for at least six months, and <5% were treated for more than a year (21).

The strength of the present study is the prospective multicentre enrolment of consecutive patients with acute DVT treated on an outpatient basis and the collection of detailed information on VTE diagnosis, VTE risk factors, and duration of pharmacological therapy. This is the first national survey providing data on the consistency with recommendations from the ACCP 2008 consensus guidelines (15) regarding the planned duration of anticoagulation in DVT patients. A weakness of the study is that no detailed data on risk factors for bleeding were recorded. Because our population consisted of outpatients only, it is unlikely that baseline co-morbidities or bleeding risk factors were the main reasons for withholding the indefinite-duration therapy in patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT. In addition, the proportion of patients with active bleeding, heparin-allergy, heparin-induced thrombocytopenia or severe renal failure was very low (1%). Another study limitation is that no additional follow-up information on compliance, actual duration and outcome of the anticoagulation treatment was collected. It is likely that the initial plan on the treatment duration has changed in some patients; possible reasons may include difficulties in INR monitoring or bleeding complications during anticoagulation treatment, cure of a cancer, diagnosis of cancer after DVT diagnosis, significant symptomatic post-thrombotic syndrome, or patient preference. Finally, our data may not necessarily be extrapolated to other countries.

What is known about this topic?

- In patients with provoked venous thromboembolism (VTE), three-month anticoagulation therapy halves the risk of recurrence within the next year in comparison to shorter treatment periods, and in patients with unprovoked VTE, indefinite-duration therapy with conventional-intensity vitamin K antagonists reduces the risk of thrombosis recurrence by up to 90%.
- Current consensus guidelines recommend three-month anticoagulation to treat provoked or first distal deep-vein thrombosis (DVT), and indefinite-duration anticoagulation should be considered for patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT.

What does this paper add?

- Physician recommendations for planning the duration of anticoagulation therapy in outpatients with acute DVT are often inconsistent and contrast with current consensus guidelines.
- One third of the patients with first distal DVT and only 40% of patients with unprovoked proximal, unprovoked recurrent, or cancer-associated DVT were considered for an indefinite-duration anticoagulation therapy.

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In conclusion, there is a need to improve risk stratification in outpatients with acute DVT and optimise the duration of anticoagulation treatment in both patients with provoked and unprovoked DVT. Implementation efforts should include continuing medical education, local and practice-specific guidelines for hospital and private practice physicians, and risk assessment models. Additionally, future research is necessary to investigate the reasons for the observed large variation in the planned duration of treatment, including a systematic questioning the physicians as to the reasons for their choices.

Conflict of interest

This study was supported by sanofi-aventis (suisse) sa, Meyrin, Switzerland. Data collection, data management and database entry was independent from the sponsor. Dr. Spirk is an employee of sanofi-aventis (suisse) sa, Meyrin, Switzerland.

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